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10/085,564	02/26/2002	Keith K. Daellenbach	BJT 332	8968

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EXAMINER	
SCHELL, LAURA C	
ART UNIT	PAPER NUMBER
3767	
MAIL DATE	DELIVERY MODE
06/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/085,564	DAELLENBACH, KEITH K.	
	Examiner	Art Unit	
	LAURA C. SCHELL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25,33 and 35-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25,33 and 35-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9, 14, 15, 18, 33 and 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tom (US Patent No. 7,211,063) in view of Glines et al. (US Patent No. 6,716,190). Tom discloses the device substantially as claimed including a device that is capable of being used for needle-free jet injection for delivering a fluid into an internal organ (Fig. 1; the abstract and col. 1, lines 16-20 disclose that the device is used for treating an internal organ such as the heart; col. 3, lines 35-40 disclose that the device can be used for needle-free injection), the device comprising a rigid end effector having a blunt distal end and a longitudinal axis configured into a shape (Fig. 1 discloses that the longitudinal axis of the end effector is bent at a 90 degree angle, the distal end 20 is blunt and col. 3, lines 19-20 disclose that the end effector has a rigid

shaft) and the end effector including a rigid interior wall and that the end effector is substantially rigid to maintain the shape of its longitudinal axis during use (Fig. 1, col. 3, lines 19-20).

While Tom discloses that the device may be equipped similarly to other well known devices and used for the therapeutic effect of needle-less injection (col. 3, lines 44-48), Tom does not specifically disclose physical elements pertaining to needle-less injection such as a fluid reservoir, lumen, plurality of orifices, etc. Glines, however, discloses a needle-less injector (Figs. 8a-8c) with a blunt distal end (230), a longitudinal axis (axis extending through 223), a plurality of orifices at the distal end (232), an interior wall (interior wall that surrounds 223) that forms a fluid channel (wall forms the fluid channel 223), the fluid channel having a cross section through which a central axis of the end effector extends (see Figs. 8b and 8c), and where the end effector allows fluid flow from the channel out through the orifices (Fig. 8c), a fluid reservoir (col. 11, line 26), an ejection mechanism (col. 11, lines 26) adapted to eject the fluid from teh reservoir through the end effector and out the orifices (Fig. 8c) with sufficient pressure to penetrate an outer organ while preserving functionality of the organ (Glines discloses in col. 12, lines 12-30 that the injection pressure can be chosen so that it will inject to a desired depth and also chosen so that it won't traumatize the tissue site) and without penetration of the outer surface of the organ by the end effector (Fig. 8c). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Tom by looking to Glines for the well known physical elements that make up a needle-less injector, such as the reservoir, orifices, fluid channel, etc. since these

are known to be included in needle-less injectors in the art and therefore it would have been obvious to equip the needle-less injector of Tom with these, especially since Tom discloses in col. 3, lines 35-48 that the device can be used for needle-free injection and would include all the necessary equipment as in known in the art.

In reference to claim 2, Tom discloses that the end effector includes a straight shaft section and a distal section (Fig. 1).

In reference to claims 3 and 4, Tom in view of Glines discloses that all of the orifices are located in the distal section (Glines, Fig. 8c).

In reference to claim 5, Tom in view of Glines discloses that the ejection mechanism is further adapted to allow the device to eject multiple doses of fluid without refilling the reservoir (Glines: col. 13, lines 51-54 discloses that the reservoir is configured to hold at least one dose but can also be configured to hold multiple doses as needed).

In reference to claims 6, 7 and 9, Tom discloses in the abstract and col. 1, lines 16-61 that the device is used for treating the wall of the heart. Tom, however, does not disclose that the device is used with sufficient pressure to cause a transmural lesion in the organ. Glines, however, discloses that the device may be used to treat the heart and that the injection pressure may be selected to target a specific tissue or depth of injection (col. 12, lines 12-30) and further discloses treating transmural lesions in the heart (Fig. 8c). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Tom's use of the device to specify a

specific injection pressure and target tissue, as taught by Glines, in order to target a specific tissue for a specific treatment.

In reference to claim 8, Tom in view of Glines discloses that the fluid injected may be ethanol (Glines col. 8, line 44).

In reference to claim 14, Tom discloses that the distal section lies at an angle between 30 and 90 degrees relative to the shaft (Fig. 1).

In reference to claims 15 and 43, Tom in view of Glines discloses that at least a portion of the distal section and the longitudinal axis of the distal section lies at an angle of approximately 45 degrees relative to the longitudinal axis of the straight shaft section (Fig. 8d of Glines discloses an embodiment of an end effector in which the distal end is at approximately 45 degrees to the straight shaft section).

In reference to claim 18, Tom in view of Glines discloses that the rows are offset from each other (Fig. 6b of Glines discloses an end effector with the orifices in offset rows).

In reference to claim 33, Tom in view of Glines discloses that the fluid channel is cylindrical (Glines in Fig. 8c discloses that 223 is cylindrical).

In reference to claim 40, Tom in view of Glines discloses that the longitudinal axis of the distal section is collinear with a longitudinal axis of the straight shaft section (Figs. 8a and 8b of Glines disclose that the distal and straight shaft sections are collinear and therefore their longitudinal axes are collinear as well).

In reference to claim 41, Tom discloses that at least a portion of the longitudinal axis of the distal section is not collinear with a longitudinal axis of the straight shaft section (Fig. 1 of Tom).

In reference to claim 42, Tom discloses that at least a portion of the longitudinal axis of the distal section lies at an angle between 30 and 90 degrees relative to at least a portion of the longitudinal axis of the straight shaft section (Fig. 1 of Tom).

Claims 19, 20, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tom (US Patent No. 7,211,063) in view of Glines et al. (US Patent No. 6,716,190). Tom discloses the device substantially as claimed including a device that is capable of being used for needle-free jet injection for delivering a fluid into an internal organ through the outer surface of the organ and into the internal organ without penetration of the organ (Fig. 1; the abstract and col. 1, lines 16-20 disclose that the device is used for treating an internal organ such as the heart; col. 3, lines 35-40 disclose that the device can be used for needle-free injection and the abstract discloses that the device is used for treating the organ without penetrating the organ), the device comprising a rigid end effector and rigid shaft having a blunt distal end and a longitudinal axis configured into a shape (Fig. 1 discloses that the longitudinal axis of the end effector is bent at a 90 degree angle, the distal end 20 is blunt and col. 3, lines 19-20 disclose that the end effector has a rigid shaft) and the end effector including a

rigid interior wall and that the end effector is substantially rigid to maintain the shape of its longitudinal axis during use (Fig. 1, col. 3, lines 19-20).

While Tom discloses that the device may be equipped similarly to other well known devices and used for the therapeutic effect of needle-less injection (col. 3, lines 44-48), Tom does not specifically disclose physical elements pertaining to needle-less injection such as a fluid channel, plurality of orifices, etc. Glines, however, discloses a needle-less injector (Figs. 8a-8c) with a blunt distal end (230), a longitudinal axis (axis extending through 223), a plurality of orifices at the distal end (232), an interior wall (interior wall that surrounds 223) that forms a tubular fluid channel (wall forms the fluid channel 223), the tubular fluid channel having a cross section through which a central axis of the end effector extends (see Figs. 8b and 8c), and where the end effector allows fluid flow from the channel out through the orifices (Fig. 8c). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Tom by looking to Glines for the well known physical elements that make up a needle-less injector, such as the reservoir, orifices, fluid channel, etc. since these are known to be included in needle-less injectors in the art and therefore it would have been obvious to equip the needle-less injector of Tom with these, especially since Tom discloses in col. 3, lines 35-48 that the device can be used for needle-free injection and would include all the necessary equipment as in known in the art. Also, while Tom discloses that the shaft is rigid (col. 3, lines 19-20), Tom does not disclose that the rigid shaft would extend between the injection device and the plurality of orifices. Glines, however, discloses that the injection device is located within the handle portion (Fig. 8a,

col. 20, lines 6-9) and that the orifices are located at the distal end of the shaft (Fig. 8c). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have applied the same arrangement to the rigid shaft and body/handle portion of Tom, as taught by Glines, since Tom discloses that the handle portion of the device may be equipped with the well-known devices to provide the desired therapeutic effect of needle-less injection (col. 3, lines 35-48). It therefore would be obvious that the injection device would be located in the handle and that the rigid shaft would be located between the handle/injection device and the plurality of orifices at the distal end of the device.

In reference to claim 20, Tom discloses that the end effector includes a straight section and a distal section (Fig. 1).

In reference to claims 24 and 25, Tom discloses that the distal section is angled and curved relative to the straight section (Fig. 1).

Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tom (US Patent No. 7,211,063) in view of Glines (US Patent No. 6,716,190). Tom in view of Glines discloses the device substantially as claimed including that the device is used for needle-free injection, however, Tom in view of Glines does not disclose the length of the distal section/end effector, or the outer and inner diameters of the end effector. It would have been obvious to one of ordinary skill in the art to form the device with the claimed lengths and diameters since it has been held that discovering an

optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980).

Claims 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tom (US Patent No. 7,211,063) in view of Glines (US Patent No. 6,716,190). Tom in view of Glines discloses the device substantially as claimed including that the device is used for needle-free injection, which by definition occurs at higher pressures in order to produce enough force on the fluid to eject into the tissue (col. 3, lines 35-40). Tom in view of Glines, however, does not disclose the specific pressures of less than 4000, 2100 or 1100 psig nor the specific dimensions of the device, such as specific lengths and diameters of parts. It would have been obvious to one of ordinary skill in the art to eject fluid from the device at pressures less than 4000, 2100 or 1100 psig it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980).

Claims 16, 17, 21-23, 35, 36, 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tom (US Patent No. 7,211,063) in view of Glines (US Patent No. 6,716,190) and further in view of Paskar (US Patent No. 6,623,449). Tom in view of Glines discloses the device substantially as claimed including a rigid shaft and end effector (Fig. 1 of Tom) and that the device may be used for needle-less injection and

may be equipped with well known devices to produce the needle-less injection therapy (col. 3, lines 35-48 of Tom). Glines discloses the well known devices/elements used to produce the needle-less injection, such as all of the plurality of orifices at the distal end of the needle-less injector (Fig. 8c). Tom in view of Glines, however, does not disclose that the orifices are located along the side of the distal end of the end effector. Paskar, however, discloses an end effector (Fig. 16) which has orifices (134) arranged in multiple offset rows along the length of the end effector. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device taught by Tom in view of Glines with the end effector with the arrangement of orifices, as taught by Paskar, in order to provide a device which could be used to cover and treat more area of the tissue and thus provide a faster and more efficient treatment.

Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Menne et al. (US Patent No. 5,840,061) in view of Tom (US Patent No. 7,211,063). Menne discloses a needle-free jet injection device (Fig. 3) for delivering a fluid into a selected internal tissue, the device comprising a body (Fig. 3, the body is being interpreted as the proximal end portion of 9 the proximal end of the body starting where it screws into the block portion where 19 is located and the distal end of the body is being interpreted as the portion where rod 8 ends and the unobstructed portion of cavity 1 begins); a longitudinally rigid elongate member (the longitudinally rigid elongate member is being interpreted as the portion of 9 where rod 8 ends and cavity portion 1 begins and extends

all the way to the distal tip of 9) extending away from the body to a blunt distal end (distal end near 17 is blunt), the longitudinally elongate member comprising: a sidewall (sidewall where 2 is located), a central longitudinal axis configured into a shape (Fig. 3), wherein the longitudinally rigid elongate member is sufficiently rigid to maintain the shape of its central longitudinal axis during use (Fig. 3), at least one injection orifice (2) disposed on the sidewall, wherein the at least one injection orifice is oriented generally laterally to the central longitudinal axis (Fig. 3), a fluid channel (1) extending substantially all the way from the body to the at least one injection orifice, wherein the central longitudinal axis is within the fluid in the fluid channel substantially all the way from the body to the at least one injection orifice (col. 5, lines 62-65 disclose that the dimension of the pressure chamber (1) may be selected based on a desired dimension, therefore it is possible that the pressure chamber's volume may be selected so that the length of the chamber is greater than the length of the portion of the body where the central axis is not located within the fluid. Furthermore, Fig. 5 discloses an embodiment in which the pressure chamber length is substantially larger than the length of the portion of the body in which the central axis is not within the fluid of the fluid channel (Fig. 5 discloses that the combined length of chamber 1 and 2 is longer). Therefore it is possible that the dimension of 1 may be selected such that the central axis resides within the fluid in the fluid channel substantially all the way from the body to the at least one injection orifice.), a straight shaft section (Fig. 3), and a distal section (distal section is near 2), at least one injection orifice (2) is disposed on the distal section, and the longitudinally rigid elongate member is adapted to be positioned with the at least on

injection orifice adjacent the selected internal tissue; a fluid reservoir (the fluid reservoir is connected at 19 as described in col. 5, lines 7-8) in communication with the fluid channel; and an ejection mechanism (Fig. 1,4 is the piston/ejection mechanism) disposed within the body, wherein the ejection mechanism is adapted to eject the fluid from the fluid reservoir through the fluid channel and out the at least one injection orifice with sufficient pressure to penetrate the selected internal tissue (col. 1, lines 50-55) while preserving functionality of the tissue and without penetration of the selected internal tissue by the longitudinally rigid elongate member (col. 6, lines 41-42). Menne, however, does not disclose that the distal end of the device is not collinear with the longitudinal axis of the straight shaft section. Tom, however, discloses a needle-free jet injection device in which the distal section is bent at an angle relative to the straight shaft section (Fig. 1). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Menne by bending the distal portion of the device at an angle relative to the straight shaft section, as taught by Tom, in order to provide a device which can reach portions of the body which can not be reached by a device that is not bent, thereby increasing the number of treatment areas and types of treatment that are possible with the device.

Response to Arguments

Applicant's arguments filed 3/5/2009 have been fully considered but they are not persuasive. The examiner has reviewed Applicant's arguments, however, it is still the examiner's position that the combination of Tom in view of Glines and Paskar as well as

the combination of Menne in view of Tom, are obvious combinations. Please see rejection above as well as the arguments in the previous office action. With regard to newly amended claim 45, it is still the examiner's position that Menne in view of Tom is obvious, please see the modified rejection above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura C Schell/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
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